Exhibit C

Bueker, John P.

From: Bueker, John P.
Sent: Friday, January 25, 2008 2:54 PM
To: 'laurie.oberembt@usdoj.gov'
Cc: 'Eric Gortner'; 'sreid@kelleydrye.com'; 'dstorborg@JonesDay.com'; Montgomery, John T.; Nemirow, Kim; Bueker, John P.
Subject: New York Counties FUL Discovery

Laurie,

I appreciate your update on the status of the promised document production and will await a further report. As you know, we have a March 31, 2008 discovery cut-off for FUL discovery in the New York Counties case. Accordingly, I am hopeful that CMS/DOJ will manage to resolve quickly the confidentiality issue with the pricing compendia and be in a position to produce the promised FUL materials next week. As it seems to me that the hardcopy document production should be largely unaffected by the confidentiality issue that you described, I will still expect to receive the hardcopy document production by the end of next week as we had agreed.

Further to our conversation of this morning, please let me know about gaining access to the programming logic or code for the "FULs application" that Sue Gaston described during her deposition yesterday. Our subpoena certainly seeks this information. More fundamentally, according to Ms. Gaston, the programming logic may provide the only written record of all of the criteria that CMS used to screen drugs for FULs. It also may helpful, and the most efficient way, to quickly narrow the issues for discovery. On a related note, Ms. Gaston identified Donna Kaufman as the computer support person most knowledgeable about the PC-based "FULs application" that CMS implemented in approximately 1995.

As I mentioned, Ms. Gaston identified, in addition to herself, two individuals who were responsible for establishing FULs during the time period relevant for discovery in the New York Counties case -- Cindy Bergin (formerly Cindy Pelter) and Gayle Sexton. We would like to depose both in the context of the New York Counties case. I understand both continue to be CMS employees. Will you accept service of subpoena on their behalf or shall I serve the HHS General Counsel's Office? We will, of course, coordinate these depositions with defendants in other AWP cases to the extent possible. To that end, I am copying counsel for Abbott, Dey, and Roxane on this e-mail so they can stay involved in the scheduling of those depositions. In our subpoenas, we will select mid-February dates for these depositions but, as I said this morning, will be flexible on the timing to the extent that we can be consistent the constraints imposed by our discovery cut-off. The New York Counties defendants would also like to depose Peter Rodler, who I understand has retired from CMS because, according to Ms. Gaston, he is the first person that she is aware of who was involved in establishing FULs and may be able to better explain the various criteria used in setting them that have apparently developed at CMS over time. We will endeavor to serve Mr. Rodler with a subpoena and keep you informed of our progress. Finally, Larry Reed apparently had some involvement in establishing FULs. I will check with other defense counsel about the scheduling of his deposition, but in light of our timing we may need to follow-up with you on the scheduling of that deposition.

Please keep me informed of the status of CMS's document production and let me know whether you will accept service of the deposition subpoenas described above.

Thanks,

John

John P. Bueker
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February 8, 2008

John P. Bueker
(617) 951-7951
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BY HAND

Kerry N. Weems
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Dept. of Health and Human Services
200 Independence Ave., S.W., Suite 314G
Washington, DC 20201

James C. Stansel, Esq.
Acting General Counsel
Office of the General Counsel
U.S. Dept. of Health and Human Services
200 Independence Ave., S.W., Suite 722A
Washington, DC 20201

Re: *City of New York* v. *Abbott Labs.*; MDL No. 1456; 01-CV-12257-PBS

Dear Dr. Weems and Mr. Stansel:

I am counsel to Schering-Plough Corporation, Schering Corporation and Warrick Pharmaceuticals Corporation (the "Warrick Defendants") in the above-referenced matter (the "NY Counties AWP matter") and write to you on behalf of all defendants in that matter regarding defendants' request for the oral deposition testimony of two Center for Medicare & Medicaid Services ("CMS") employees, Gayle Sexton and Cindy Bergin, and one former CMS employee, Peter Rodler.

We are making this request pursuant to the relevant *Touhy* regulation, 45 C.F.R. § 2.4. Given that Judge Saris, who is presiding over this case, has set an expedited discovery schedule ending on March 31, 2008 for matters relating to the Federal Upper Limit ("FUL"), we respectfully ask that you make a decision by February 19, 2008. In light of the discovery schedule and anticipating the Agency's willingness to make these individuals available for deposition, we enclose subpoenas for Ms. Sexton and Ms. Bergin, and will seek to serve Mr. Rodler, who we understands resides in Palm Springs, California, personally with a copy of the enclosed subpoena for his testimony. I would, of course, be willing to work with you to find mutually agreeable dates within the confines of our discovery schedule for these depositions. If no commitment is received by February 19, 2008, to make these individuals available within the discovery period – whether via a *Touhy* response or in response to the subpoenas – we will seek an order from the Court compelling a response. *See, e.g., Yosuf* v. *Smantar*, 451 F.3d 248, 251 (D.C. Cir. 2006) (motion to compel was ripe for review when government was still considering *Touhy* response and appellant had proceeded with both *Touhy* letter and subpoena).

Title 45, Section 2.4 of the Code of Federal Regulations provides that any requests for testimony of an employee of the Department of Health & Human Services ("DHHS") "must state

the nature of the requested testimony, why the information sought is unavailable by any other means, and why the testimony would be in the interest of the DHHS or the federal government." Such a request should be granted if it "would promote the objectives of the Department." *See* 45 C.F.R. § 2.3. Such is the case here.

1. Nature of the Requested Testimony

Defendants seek the testimony of Ms. Sexton, Ms. Bergin, and Mr. Rodler regarding their knowledge of what criteria were used to set and maintain FULs for nine, specifically identified multi-source pharmaceutical products covered by Medicaid, how those criteria were applied to establish FULs for those drugs, and whether the same criteria were used and applied consistently to establish FULs for all other drugs subject to FULs. A list of the nine multi-source drugs that are most particularly the subject of this request is attached hereto as Exhibit A. Judge Saris has deemed these issues essential to the NY Counties AWP matter and, therefore, made them the focus of fast-tracked discovery. *See City of New York* v. *Abbott Labs.*, MDL No. 1456; 01-CV-12257-PBS, CMO No. 33, (Docket No. 4745) (Sept. 14, 2007) ("CMO 33").

During a January 24, 2008 deposition, CMS employee Susan E. Gaston, Team Lead for Dispute Resolution of the Medicaid Drug Rebate Program (2003 to the present) and former Health Insurance Specialist (1991 to 2003), identified Ms. Sexton, Ms. Bergin and Mr. Rodler as the CMS employees responsible for manually setting and maintaining FULs according to certain criteria. *See* 1/24/08 Dep. of S. Gaston at 46:1-47:4; 49:1-3 & 223:16-224:8 ("Gaston Dep."). Ms. Gaston was responsible for setting FULs from 1991 through the mid to late 1990s.

Ms. Gaston testified that Mr. Rodler was responsible for managing the FULs from their inception in 1987 until his retirement in the early 1990s and that Mr. Rodler taught Ms. Gaston how to "handle" the FULs. *Id.* at 225:16-21 and 249:10-11. According to Ms. Gaston, Ms. Bergin was responsible for implementing the criteria used to establish FULs from the mid to late 1990s through 2003. *Id.* at 225:7-12. After being trained by Ms. Bergin, Ms. Sexton took over managing the administration and implementation of the FUL program in 2003, and remains primarily responsible for establishing FULs today. *Id.* at 49:1-3 & 226:3-7.

2. Availability from Other Means

The information that we seek to obtain through the oral testimony of these individuals is not available through other means. The FUL regulation, 42 C.F.R. § 477.332, and its regulatory history do not provide information about the specific criteria used by CMS to implement the FUL regulation nor do they explain how these criteria have been applied over time.

Ms. Gaston testified that FULs were and are established by a two step process. First, a computer program identifies drugs that are deemed eligible for a FUL in accordance with the terms of the applicable regulation and certain additional, unwritten criteria (*e.g.*, that injectible drugs and unit doses were not eligible for FULs) that those at CMS responsible for establishing FULs felt were in keeping with the spirit of the regulation. Second, Ms. Gaston, Ms. Sexton,

Ms. Bergin, and Mr. Rodler during their respective tenures would "manually review" the computer program's output based on an exceptions report to determine whether a FUL should be established for the drugs identified by the program. *See* Gaston Dep. at 225:19-21 & 233:10-234:18 ("Then we apply some manual review just to assure we have – there's some edits and I can't remember all of those....But basically there's a lot of manual review that's included before the final FUL listing will come out.") Importantly, Ms. Gaston testified that the FUL manual review required the application of certain additional criteria that are not memorialized in any written policy memorandum or other document. *Id.* at 250:2-6 & 252:3-10.

Ms. Gaston's deposition testimony was insufficient to establish the criteria used to set and maintain FULs. Although Ms. Gaston testified that a "manual review" by the CMS employees primarily responsible for establishing FULs (Gaston, Sexton, Bergin, or Rodler) was required for certain drugs "where the pricing might not look right," she repeatedly testified that she could not "remember" all of the elements of this manual review process. *See, e.g., id.* at 234:7-18. Indeed, the only source of information for what criteria were applied during this manual review seems to be the live testimony of these individuals who were primarily responsible for CMS' implementation of the FUL program. *Id.*

Mr. Rodler, the former CMS employee responsible for setting FULs at their inception, is in a unique position to testify about the rules and criteria applied during CMS' initial implementation of the automated "FULs program" and how additional criteria were "manually" implemented during his tenure. Ms. Gaston recalled that certain criteria were well-developed and already engrained in the process of, and program for, setting FULs at the time she assumed primary responsibility for the process; it is, thus, quite possible that Mr. Rodler established and implemented certain criteria that were not at all transparent to Ms. Gaston and of which she was never aware. Through OBRA '90 and OBRA '93, Congress altered and imposed new restrictions on how CMS was to set FULs. Ms. Bergin, responsible for manually applying CMS' FUL criteria from the mid to late 1990s through 2003, should be best able to testify about the substance and application of these criteria during that period, including any changes to the criteria for establishing FULs. Ms. Sexton, primarily responsible for establishing FULs since 2003, will also be able to testify about the criteria used to establish FULs and, further, will be able to testify regarding the impact of the Deficit Reduction Act of 2005, 42 C.F.R. § 447.5000, on the criteria for establishing FULs.

As you may know, on December 20, 2007, the Warrick Defendants subpoenaed documents from CMS regarding the criteria used in setting FULs. Although CMS has not yet fully complied with that subpoena, in light of Ms. Gaston's testimony, it is clear that not all of the criteria used by CMS to implement FULs were not memorialized in any written document, and that any production made by CMS in response to the Warrick Defendants' subpoena will not be sufficient to supply the information sought and deemed, by the Court, to be important to the resolution of issues at the core of the NY Counties AWP matter. The testimony of Ms. Sexton, Ms. Bergin, and Mr. Rodler is, therefore, critical to the discovery of what criteria were used to set and maintain FULs and how those criteria were applied.

3. Interests of DHHS and Federal Government

Allowing Ms. Sexton, Ms. Bergin, and Mr. Rodler to testify is in the best interest of DHHS and the federal government as provided for in 45 C.F.R. § 2.4. One of the stated goals of DHHS is to "protect[] the health of all Americans and provid[e] essential human services, especially for those who are least able to help themselves," and one of the primary functions of CMS is to set and maintain the FULs for Medicaid reimbursement of multi-source pharmaceutical products.

The NY Counties AWP matter is brought by more than 40 counties in New York State alleging, in part, that defendants committed fraud on the state's Medicaid program with respect to multi-source drugs subject to FULs. Judge Saris, who is presiding over this case, recognized that a complete understanding of the methodology behind the setting of FULs is key to determining the veracity of plaintiffs' claims. *See* July 26, 2007 Status Conference Tr. at 28:13-15 & 31:6-7.

Indeed, in April 2007, Judge Saris dismissed without prejudice plaintiffs' claims relating to drugs reimbursed based on FULs in part because "the parties have failed to explain the FUL reimbursement system clearly." *In re Pharmaceutical Indus. AWP Litig.*, No. 01-CV-12257-PBS, 2007 WL 1051642, at *16 (D. Mass. April 2, 2007). Judge Saris permitted plaintiffs to re-plead their FUL allegations and allowed defendants to re-file a motion to dismiss specifically tailored to the FUL issue. May 16, 2007 Status Conference Tr. at 26:18-27:5. In addition to the motion to dismiss papers filed by the parties relating to FULs, at the Court's request, the United States filed a brief describing the regulatory requirements for setting FULs. *In re Pharmaceutical Indus. AWP Litig.*, No. 01-CV-12257-PBS (Docket No. 4413) (June 28, 2007).

However, despite the extensive briefing by the parties and the United States about the criteria and methodology used by CMS for setting and maintaining FULs, Judge Saris still found that the methodology employed by CMS to set and maintain FULs was unclear. Therefore, she was unwilling to make a determination on a motion to dismiss and ordered expedited discovery on a limited number of drugs subject to FULs to "figure out the methodology" used by CMS to set and maintain FULs. July 26, 2007 Status Conference Tr. at 28:13-15. Pursuant to CMO 33, each party proposed five drugs as subjects of FUL discovery to be completed by March 31, 2008. *See* CMO No. 33. It is as part of this discovery that defendants seek the deposition testimony of Ms. Sexton, Ms. Bergin, and Mr. Rodler.

In light of Ms. Gaston's testimony that Ms. Sexton, Ms. Bergin, and Mr. Rodler were primarily responsible for establishing and maintaining CMS' criteria for setting FULs and that the criteria are not documented in writing, the deposition testimony of these CMS witnesses is critical to carrying out Judge Saris' order to "figure out the methodology" for how CMS sets FULs.

* * *

For the foregoing reasons, 45 C.F.R. § 2 warrants your authorizing us to subpoena Ms. Sexton, Ms. Bergin, and Mr. Rodler in the above-referenced litigation. Given the time sensitive nature of this litigation, we respectfully ask that you approve our request as soon as possible, and no later than February 19, 2008. If you have any concerns, we would be pleased to speak with you at your earliest convenience.

Very truly yours,

John P. Bueker

Enclosure

cc: Laurie A. Oberempt, Esq. (by e-mail)
Senior Trial Counsel
Commercial Litigation Branch
Department of Justice
601 D Street, N.W., 9th Floor
Washington, D.C. 20004

Carol Bennett, Esq. (by hand)
Deputy Associate General Counsel
Health and Human Services
330 Independence Avenue, S.W.
Suite 5300
Washington, DC 20201

AO88 (Rev. 12/06) Subpoena in a Civil Case

Issued by the

UNITED STATES DISTRICT COURT

DISTRICT OF COLUMBIA

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION

V.

THIS DOCUMENT RELATES TO CONSOLIDATED NEW YORK COUNTY ACTIONS

SUBPOENA IN A CIVIL CASE
MDL NO. 1456
Civil Action No. 01-12257-PBS

Case Number:[1]
Judge Patti B. Saris
(Case Pending in D. Mass.)

TO: Cindy Bergin
United States Department of Health and Human Services
200 Independence, SW
Washington, DC 20201

☐ YOU ARE COMMANDED to appear in the United States District court at the place, date, and time specified below to testify in the above case.

PLACE OF TESTIMONY	COURTROOM
	DATE AND TIME

☑ YOU ARE COMMANDED to appear at the place, date, and time specified below to testify at the taking of a deposition in the above case.

PLACE OF DEPOSITION	DATE AND TIME
Law offices of Ropes & Gray LLP, One Metro Center, 700 12th Street, NW, Suite 900, Washington, D.C. 20005-3948	3/5/2008 9:30 am

☐ YOU ARE COMMANDED to produce and permit inspection and copying of the following documents or objects at the place, date, and time specified below (list documents or objects):

PLACE	DATE AND TIME

☐ YOU ARE COMMANDED to permit inspection of the following premises at the date and time specified below.

PREMISES	DATE AND TIME

Any organization not a party to this suit that is subpoenaed for the taking of a deposition shall designate one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, and may set forth, for each person designated, the matters on which the person will testify. Federal Rules of Civil Procedure, 30(b)(6).

ISSUING OFFICER'S SIGNATURE AND TITLE (INDICATE IF ATTORNEY FOR PLAINTIFF OR DEFENDANT)	DATE
Carisa A. Klemeyer	2/8/2008

ISSUING OFFICER'S NAME, ADDRESS AND PHONE NUMBER
Carisa A. Klemeyer, Ropes & Gray LLP, One International Place, Boston, MA 02110. (617) 951-7000. Attorney for Defendants Schering-Plough Corporation, Schering Corporation, and Warrick Pharmaceuticals Corporation.

(See Rule 45, Federal Rules of Civil Procedure, Subdivisions (c), (d), and (e), on next page)

[1] If action is pending in district other than district of issuance, state district under case number.

AO88 (Rev. 12/06) Subpoena in a Civil Case

PROOF OF SERVICE

DATE PLACE

SERVED

SERVED ON (PRINT NAME) MANNER OF SERVICE

SERVED BY (PRINT NAME) TITLE

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Proof of Service is true and correct.

Executed on _____
DATE

SIGNATURE OF SERVER

ADDRESS OF SERVER

Rule 45, Federal Rules of Civil Procedure, Subdivisions (c), (d), and (e), as amended on December 1, 2006:

(c) PROTECTION OF PERSONS SUBJECT TO SUBPOENAS.

(1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issued shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction, which may include, but is not limited to, lost earnings and a reasonable attorney's fee.

(2) (A) A person commanded to produce and permit inspection, copying, testing, or sampling of designated electronically stored information, books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for deposition, hearing or trial.

(B) Subject to paragraph (d)(2) of this rule, a person commanded to produce and permit inspection, copying, testing, or sampling may, within 14 days after service of the subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the subpoena written objection to producing any or all of the designated materials or inspection of the premises — or to producing electronically stored information in the form or forms requested. If objection is made, the party serving the subpoena shall not be entitled to inspect, copy, test, or sample the materials or inspect the premises except pursuant to an order of the court by which the subpoena was issued. If objection has been made, the party serving the subpoena may, upon notice to the person commanded to produce, move at any time for an order to compel the production, inspection, copying, testing, or sampling. Such an order to compel shall protect any person who is not a party or an officer of a party from significant expense resulting from the inspection, copying, testing, or sampling commanded.

(3) (A) On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it

(i) fails to allow reasonable time for compliance;

(ii) requires a person who is not a party or an officer of a party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transacts business in person, except that, subject to the provisions of clause (c)(3)(B)(iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held;

(iii) requires disclosure of privileged or other protected matter and no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) If a subpoena

(i) requires disclosure of a trade secret or other confidential research, development, or commercial information, or

(ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party, or

(iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena or, if the party in whose behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

(d) DUTIES IN RESPONDING TO SUBPOENA.

(1) (A) A person responding to a subpoena to produce documents shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the demand.

(B) If a subpoena does not specify the form or forms for producing electronically stored information, a person responding to a subpoena must produce the information in a form or forms in which the person ordinarily maintains it or in a form or forms that are reasonably usable.

(C) A person responding to a subpoena need not produce the same electronically stored information in more than one form.

(D) A person responding to a subpoena need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or to quash, the person from whom discovery is sought must show that the information sought is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) (A) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial-preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the demanding party to contest the claim.

(B) If information is produced in response to a subpoena that is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has and may not use or disclose the information until the claim is resolved. A receiving party may promptly present the information to the court under seal for a determination of the claim. If the receiving party disclosed the information before being notified, it must take reasonable steps to retrieve it. The person who produced the information must preserve the information until the claim is resolved.

(e) CONTEMPT. Failure of any person without adequate excuse to obey a subpoena served upon that person may be deemed a contempt of the court from which the subpoena issued. An adequate cause for failure to obey exists when a subpoena purports to require a nonparty to attend or produce at a place not within the limits provided by clause (ii) of subparagraph (c)(3)(A).

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Issued by the

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In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION

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MDL NO. 1456

Civil Action No. 01-12257-PBS

Case Number:[1]

Judge Patti B. Saris

(Case Pending in D. Mass.)

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ISSUING OFFICER'S SIGNATURE AND TITLE (INDICATE IF ATTORNEY FOR PLAINTIFF OR DEFENDANT)	DATE
Carisa A. Klemeyer	2/8/2008

ISSUING OFFICER'S NAME, ADDRESS AND PHONE NUMBER
Carisa A. Klemeyer, Ropes & Gray LLP, One International Place, Boston, MA 02110. (617) 951-7000. Attorney for Defendants Schering-Plough Corporation, Schering Corporation, and Warrick Pharmaceuticals Corporation.

(See Rule 45, Federal Rules of Civil Procedure, Subdivisions (c), (d), and (e), on next page)

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(2) (A) A person commanded to produce and permit inspection, copying, testing, or sampling of designated electronically stored information, books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for deposition, hearing or trial.

(B) Subject to paragraph (d)(2) of this rule, a person commanded to produce and permit inspection, copying, testing, or sampling may, within 14 days after service of the subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the subpoena written objection to producing any or all of the designated materials or inspection of the premises — or to producing electronically stored information in the form or forms requested. If objection is made, the party serving the subpoena shall not be entitled to inspect, copy, test, or sample the materials or inspect the premises except pursuant to an order of the court by which the subpoena was issued. If objection has been made, the party serving the subpoena may, upon notice to the person commanded to produce, move at any time for an order to compel the production, inspection, copying, testing, or sampling. Such an order to compel shall protect any person who is not a party or an officer of a party from significant expense resulting from the inspection, copying, testing, or sampling commanded.

(3) (A) On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it

(i) fails to allow reasonable time for compliance;

(ii) requires a person who is not a party or an officer of a party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transacts business in person, except that, subject to the provisions of clause (c)(3)(B)(iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held;

(iii) requires disclosure of privileged or other protected matter and no exception or waiver applies; or

(iv) subjects a person to undue burden.

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(i) requires disclosure of a trade secret or other confidential research, development, or commercial information, or

(ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party, or

(iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena or, if the party in whose behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

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(D) A person responding to a subpoena need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or to quash, the person from whom discovery is sought must show that the information sought is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) (A) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial-preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the demanding party to contest the claim.

(B) If information is produced in response to a subpoena that is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has and may not use or disclose the information until the claim is resolved. A receiving party may promptly present the information to the court under seal for a determination of the claim. If the receiving party disclosed the information before being notified, it must take reasonable steps to retrieve it. The person who produced the information must preserve the information until the claim is resolved.

(e) CONTEMPT. Failure of any person without adequate excuse to obey a subpoena served upon that person may be deemed a contempt of the court from which the subpoena issued. An adequate cause for failure to obey exists when a subpoena purports to require a nonparty to attend or produce at a place not within the limits provided by clause (ii) of subparagraph (c)(3)(A).

AO88 (Rev. 12/06) Subpoena in a Civil Case

Issued by the

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION

V.

THIS DOCUMENT RELATES TO CONSOLIDATED NEW YORK COUNTY ACTIONS

TO: Peter Rodler
2943 East Alta Loma
Palm Springs, CA 92664

SUBPOENA IN A CIVIL CASE

MDL NO. 1456
Civil Action No. 01-12257-PBS

Case Number:[1]

Judge Patti B. Saris
(Case Pending in D. Mass.)

☐ YOU ARE COMMANDED to appear in the United States District court at the place, date, and time specified below to testify in the above case.

PLACE OF TESTIMONY	COURTROOM
	DATE AND TIME

☑ YOU ARE COMMANDED to appear at the place, date, and time specified below to testify at the taking of a deposition in the above case.

PLACE OF DEPOSITION	DATE AND TIME
Offices of Maxene Weinberg Agency, 74-399 Highway 111, Palm Desert, CA 92260	3/18/2008 9:30 am

☐ YOU ARE COMMANDED to produce and permit inspection and copying of the following documents or objects at the place, date, and time specified below (list documents or objects):

PLACE	DATE AND TIME

☐ YOU ARE COMMANDED to permit inspection of the following premises at the date and time specified below.

PREMISES	DATE AND TIME

Any organization not a party to this suit that is subpoenaed for the taking of a deposition shall designate one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, and may set forth, for each person designated, the matters on which the person will testify. Federal Rules of Civil Procedure, 30(b)(6).

ISSUING OFFICER'S SIGNATURE AND TITLE (INDICATE IF ATTORNEY FOR PLAINTIFF OR DEFENDANT)	DATE
Carisa A. Klemeyer	2/8/2008

ISSUING OFFICER'S NAME, ADDRESS AND PHONE NUMBER

Carisa A. Klemeyer, Ropes and Gray LLP, One International Place, Boston, MA 02110. (617) 951-7000. Attorney for Defendants Schering-Plough Corporation, Schering Corporation, and Warrick Pharmaceuticals Corporation.

(See Rule 45, Federal Rules of Civil Procedure, Subdivisions (c), (d), and (e), on next page)

[1] If action is pending in district other than district of issuance, state district under case number.

AO88 (Rev. 12/06) Subpoena in a Civil Case

PROOF OF SERVICE

DATE PLACE

SERVED

SERVED ON (PRINT NAME) MANNER OF SERVICE

SERVED BY (PRINT NAME) TITLE

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Proof of Service is true and correct.

Executed on _____
DATE

_____
SIGNATURE OF SERVER

_____
ADDRESS OF SERVER

Rule 45, Federal Rules of Civil Procedure, Subdivisions (c), (d), and (e), as amended on December 1, 2006:

(c) PROTECTION OF PERSONS SUBJECT TO SUBPOENAS.

(1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issued shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction, which may include, but is not limited to, lost earnings and a reasonable attorney's fee.

(2) (A) A person commanded to produce and permit inspection, copying, testing, or sampling of designated electronically stored information, books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for deposition, hearing or trial.

(B) Subject to paragraph (d)(2) of this rule, a person commanded to produce and permit inspection, copying, testing, or sampling may, within 14 days after service of the subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the subpoena written objection to producing any or all of the designated materials or inspection of the premises—or to producing electronically stored information in the form or forms requested. If objection is made, the party serving the subpoena shall not be entitled to inspect, copy, test, or sample the materials or inspect the premises except pursuant to an order of the court by which the subpoena was issued. If objection has been made, the party serving the subpoena may, upon notice to the person commanded to produce, move at any time for an order to compel the production, inspection, copying, testing, or sampling. Such an order to compel shall protect any person who is not a party or an officer of a party from significant expense resulting from the inspection, copying, testing, or sampling commanded.

(3) (A) On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it

(i) fails to allow reasonable time for compliance;

(ii) requires a person who is not a party or an officer of a party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transacts business in person, except that, subject to the provisions of clause (c)(3)(B)(iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held;

(iii) requires disclosure of privileged or other protected matter and no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) If a subpoena

(i) requires disclosure of a trade secret or other confidential research, development, or commercial information, or

(ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party, or

(iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena or, if the party in whose behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

(d) DUTIES IN RESPONDING TO SUBPOENA.

(1) (A) A person responding to a subpoena to produce documents shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the demand.

(B) If a subpoena does not specify the form or forms for producing electronically stored information, a person responding to a subpoena must produce the information in a form or forms in which the person ordinarily maintains it or in a form or forms that are reasonably usable.

(C) A person responding to a subpoena need not produce the same electronically stored information in more than one form.

(D) A person responding to a subpoena need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or to quash, the person from whom discovery is sought must show that the information sought is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) (A) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial-preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the demanding party to contest the claim.

(B) If information is produced in response to a subpoena that is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has and may not use or disclose the information until the claim is resolved. A receiving party may promptly present the information to the court under seal for a determination of the claim. If the receiving party disclosed the information before being notified, it must take reasonable steps to retrieve it. The person who produced the information must preserve the information until the claim is resolved.

(e) CONTEMPT. Failure of any person without adequate excuse to obey a subpoena served upon that person may be deemed a contempt of the court from which the subpoena issued. An adequate cause for failure to obey exists when a subpoena purports to require a nonparty to attend or produce at a place not within the limits provided by clause (ii) of subparagraph (c)(3)(A).

Bueker, John P.

From: Bueker, John P.
Sent: Friday, February 22, 2008 2:51 PM
To: 'Oberembt, Laurie (CIV)'
Cc: Bueker, John P.
Subject: CMS Document Production

Laurie,

I received your cover letter by e-mail today and look forward to receiving CMS' supplemental document production related to FUL issues. You state that the CD contains "materials pertaining to FUL calculations, including general FUL program documents." Does this mean that you are producing a copy of the computer code that runs the "FULs program"? If not, what is the status of our request to receive that code? As I have said before, the code very well may be the best record of at least the mechanical steps taken in the process of CMS' setting FULs.

The Medi-Span license has been more complicated to negotiate than I had hoped or anticipated, but I am told to expect to receive a signed agreement by Monday. As soon as I receive a signed agreement, I will fax it to agency counsel as you request. As I understand it, our obtaining a signed license agreement from Medi-Span is the only barrier remaining to CMS' completing its document production. I have asked you for similar assurances on several prior occasions and you have not told me differently. Had you, I certainly would have sought the Court's intervention before now. Please confirm that, upon receipt of the signed Medi-Span license, CMS will be in a position to complete its production promptly and let me know how long you anticipate it might take after receiving the signed license to do that. It would help defendants to schedule discovery appropriately.

Finally, on February 8, 2008, I sent a letter to Ms. Kerry Weems, Acting CMS Administrator, Mr. James Stansel, the agency's Acting General Counsel, and copied you and Ms. Carol Bennett, who I understand handles *Touhy* requests for CMS, seeking the testimony of three current or former CMS employees -- Gayle Sexton, Cindy Bergin, and Peter Rodler. I requested a response by February 19, 2008, but have not yet received one. Are you the appropriate point of contact with regard to this request? If not, please let me know with whom I should correspond before seeking the Court's assistance.

Thanks very much for you continued attention to this matter.

Very truly yours,

John

John P. Bueker
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DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations

MAR 20 2008

John P. Bueker
Ropes & Gray LLP
One International Place
Boston, MA 02110-2624

Re: Request for testimony in City of New York v. Abbott Laboratories, Inc.; MDL No. 1456; 01-CV-12257-PBS. (D. Mass.)

Dear Mr. Bueker:

I write in response to your letter to Kerry Weems, Acting Administrator of the Centers for Medicare & Medicaid Services (CMS), U.S. Department of Health and Human Services (HHS) and James C. Stansel, Acting General Counsel for HHS, in which you request the deposition testimony of current CMS employees Gail Sexton and Cindy Bergin (the former Cindy Pelter) and a former CMS employee, Peter Rodler, in the above-referenced litigation to which the government is not a party.

As current and former employees of CMS, Ms. Sexton, Ms. Bergin and Mr. Rodler are covered by the agency's "Touhy regulation," 45 C.F.R. Part 2. The HHS Touhy regulation prohibits HHS employees and former employees from providing testimony or producing documents concerning information acquired in the course of performing official duties unless "authorized by the Agency head . . . based on a determination by the Agency head, after consultation with the Office of the General Counsel, that compliance with the request would promote the objectives of the Department." 45 C.F.R. § 2.3. See United States ex rel. Touhy v. Ragen, 340 U.S. 462 (1951); Moore v. Armour Pharm. Co., 927 F.2d 1194 (11th Cir. 1991). The CMS Administrator has delegated the authority to make these determinations to the Deputy Administrator, Regional Administrators, Center Directors, and Office Directors. Pursuant to this delegation, I am responsible for deciding whether to approve your request.

Your request for testimony is made as part of litigation in, City of New York v. Abbott Laboratories, Inc.; MDL No. 1456; 01-CV-12257-PBS (D. Mass.), a matter to which the government is not a party. However, the case is one of several cases that are part of a multi-district litigation (MDL) currently before the United States District Court for the District of Massachusetts. The federal government has also filed a complaint against Abbott Laboratories, Inc. and the case, United States ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., MDL No. 1456; No. 06-CV-11337-PBS (D. Mass), is also part of the MDL. As part of discovery in the government's case, several CMS employees have been and continue to be deposed on multiple days. Those employees include Larry Reed, Technical Director, Pharmacy Team, with general oversight of the federal upper limit (FUL) program; Deirdre

Duzor, Director, Pharmacy Team; and Sue Gaston, formerly lead Pharmacy Team analyst for the FUL program and currently Team Lead for Dispute Resolution of the Medicaid Drug Rebate Program. Also, as part of discovery in the government's case, CMS has produced current and historical documents demonstrating the establishment of FULs and how FULs were calculated for certain multi-source drugs. CMS has also responded to specific discovery requests concerning the calculation of the FULs. Everything produced by CMS as part of the government's litigation is available to all the plaintiffs and defendants in the MDL, including the Warrick Defendants. Considering the prior and continuing discovery regarding FULs in the government's case, I have decided to deny testimony for Peter Rodler and Cindy Bergin because I believe that such testimony would not promote the objectives of HHS as it is duplicative of previous discovery responses, including prior deposition testimony.

However, I believe that it would promote the interests of the HHS to allow Gail Sexton, the current operator of the FUL program, to testify on the development, to the extent there has been such, of FULs for the following drugs: enalapril maleate (20 mg tablet), lorazepam (1 mg tablet), klonopin (0.5 mg tablet), albuterol (90 mcg inhaler and 0.83 mg/ml solution), metropolol (100 mg tablet), cefadroxil (500 mg tablets and capsulate), ranitidine (150 mg tablet), and isosorbide mononitrate (60 mg tablet).

HHS' approval of this request as to Gail Sexton should not be construed as an endorsement by HHS of any statements which Ms. Sexton may make in a deposition. HHS reserves the right to correct any inaccuracies that may occur by filing a brief with the court or by otherwise correcting the record in an appropriate manner.

If you have any questions about this decision, please contact Brian Kelley, of the Office of the General Counsel at (202) 205-8702.

Sincerely,

Dennis G. Smith
Director,
Center for Medicaid and State Operations